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Nos. 94-1527 and 94-1531

In the Supreme Court of the United States

OCTOBER TERM, 1995

BARR LABORATORIES, PETITIONER

v.

BURROUGHS WELLCOME CO.

NOVOPHARM, INC., AND NOVOPHARM, LTD., PETITIONERS

v.

BURROUGHS WELLCOME CO.

ON PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The question presented in No. 94-1527 is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention for purposes of federal patent law.

The questions presented in No. 94-1531 are:

1. Whether the factual record before the district court precluded the court from entering judgment as a matter of law in favor of respondent under Rule 50(a) of the Federal Rules of Civil Procedure.

2. Whether, after an invention has been conceived by an inventor, someone who tests the invention with more than ordinary skill thereby becomes a joint inventor.

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This brief is filed in response to this Court's order inviting the Solicitor General to express the views of the United States.

STATEMENT

Respondent Burroughs Wellcome Co. (Burroughs) holds patents for the use of a pharmaceutical compound called AZT (3'-azido-3'-deoxythymidine) to treat persons infected with the human immuno-deficiency virus (HIV), which causes a disease commonly known as acquired immune deficiency syndrome (AIDS). Burroughs brought suit against petitioner Barr Laboratories, Inc. (Barr) and

petitioners Novopharm, Inc., and Novopharm Ltd. (jointly Novopharm), alleging that those companies had infringed Burroughs' patents. The district court entered judgment for Burroughs (94-1527 Pet. App. 25a-37a), and the court of appeals largely affirmed the district court's decision (*id.* at 1a-23a).

1. In 1984, Burroughs commenced a research program to identify compounds that might be active against HIV, which was known to be a member of the Retroviridae or "retrovirus" family. See *Steadman's Medical Dictionary* 1720 (25th ed. 1990). Burroughs focused its research on a group of compounds known as nucleoside analogs. In October 1984, Burroughs began by screening the compounds against a class of murine (mouse) retroviruses that were thought to be analogous to HIV. Burroughs' testing revealed that administration of low concentrations of AZT produced significant activity against those retroviruses. 94-1527 Pet. App. 3a-4a.

At the time that it was carrying out the murine retrovirus screening program, Burroughs lacked the technical capability to test the compounds using the human retrovirus. However, the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), had that capability. Dr. Samuel Broder, a government scientist employed by the NIH, had developed a technique for testing potential AIDS drug treatments against clones of HIV-infected human cells. At Burroughs' request, Dr. Broder undertook to screen compounds supplied by Burroughs against his so-called ATH8 cell line. 94-1527 Pet. App. 4a.

On February 4, 1985, Burroughs supplied Dr. Broder with a sample of AZT, which Burroughs identified only as "Compound S." Two days later, before Dr. Broder had tested the compound, Burroughs prepared a draft British patent application for AZT. The draft patent application

described the use of AZT to treat patients infected with HIV, and it set out various formulations of AZT and associated dosages for administering the treatment. In mid-February 1985, shortly after Burroughs had prepared the draft patent application, one of Dr. Broder's colleagues tested "Compound S" on the ATH8 cell line. He found that the compound was extremely active against HIV. Dr. Broder informed Burroughs of the positive test results on February 20, 1985. 94-1527 Pet. App. 4a.

After receiving those positive results, Burroughs sought approval from the Food and Drug Administration (FDA) to market AZT as an AIDS treatment, and it initiated clinical trials. Burroughs filed British applications for AZT patents in March 1985, and it filed American applications for AZT patents in September 1985. In 1987, Burroughs received FDA approval to market AZT as an AIDS treatment drug. Burroughs eventually received six United States patents for the use of AZT to treat HIV-infected patients. 94-1527 Pet. App. 5a, 26a, 29a.

2. Under United States patent law, if two or more persons jointly make an invention, the patent application must name each of the joint inventors, and if a patent is issued, each inventor (or his assignee) is entitled to practice the invention. 35 U.S.C. 116, 262. See also 35 U.S.C. 256 (describing the procedure for adding omitted inventors and the consequences of a "deceptive" omission). In this case, Burroughs identified five of its own scientists as joint inventors in its AZT patent applications, but it did not name Dr. Broder or any other NIH scientist. See 94-1527 Pet. 7-8.

At the time that Burroughs filed the patent applications, and for a considerable period thereafter, the NIH scientists did not themselves assert a claim of inventorship. See 94-1527 Pet. App. 36a. In 1987, a congressional subcommittee held hearings that raised questions con-

cerning, among other things, the price that Burroughs charged for the AZT treatment. See *AIDS Issues (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 1st Sess. 1-52 (1987). Thereafter, the NIH reexamined the role that its scientists had played in testing AZT for Burroughs. Based on that review, the NIH concluded that its scientists had been joint inventors of the patented inventions and should have been named in the Burroughs patent applications. See 94-1527 Pet. 8.

In July 1991, the NIH entered into an AZT licensing agreement with Barr, which manufactures generic drugs. C.A. App. A5368. The agreement stated that the NIH had "inchoate intellectual property rights" in the Burroughs AZT patents. *Id.* at A5386 (§§ 1.02, 2.01). The NIH granted Barr a nonexclusive license to market AZT in the United States for any use approved by the FDA. *Id.* at A5371, A5384, A5387 (§ 3.01, Apps. B & D). In return, Barr agreed to pay the NIH royalties equal to a percentage of Barr's net sales, as well as certain additional sums. *Id.* at A5372-A5373, A5385 (§§ 5.01-5.03 & App. C).

The licensing agreement required Barr to assume responsibility for legal actions "to establish an inventorship/ownership interest on the part of the Government" in the inventions covered by the Burroughs patents. C.A. App. A5388 (§ 15.01). The agreement permitted Barr to count 50% of its "reasonable legal expenses" as a credit against any future royalty obligations to the NIH. *Id.* at A5385, A5388 (§ 15.01 & App. C). However, the agreement did not obligate the federal government itself to participate in the litigation. *Id.* at A5388 (§ 15.01).

3. While the NIH and Barr were negotiating the licensing agreement, Barr took steps that precipitated this patent dispute with Burroughs. In March 1991, Barr applied to the FDA under 21 U.S.C. 355(j) (1988 & Supp. V

1993) for approval to manufacture and sell a generic version of AZT. In June 1992, Novopharm, a generic drug manufacturer that did not obtain a license from the NIH, filed a similar application. The filings of those FDA applications were themselves technical acts of patent infringement under 35 U.S.C. 271(e)(2). See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 675 (1990).

Burroughs responded by suing Barr and Novopharm for patent infringement in federal district court. See 94-1527 Pet. App. 5a. Barr and Novopharm defended their actions on the ground that the NIH scientists were joint inventors and should have been named in the Burroughs patent applications. *Ibid.* Novopharm additionally contended that the omission of the NIH scientists was the result of "deceptive intent" on the part of Burroughs, rendering the patents invalid and unenforceable. *Id.* at 6a. See 35 U.S.C. 256. The dispute over joint inventorship entailed, among other things, a disagreement over when the inventions were made.

Burroughs contended that its scientists invented the patented uses of AZT no later than February 6, 1985, the date that Burroughs prepared its draft British patent application (see pp. 2-3, *supra*). In contrast, Barr and Novopharm contended that the inventive process was not complete until at least two weeks later, on February 20, 1985, after Dr. Broder and his NIH colleague screened "Compound S" against the ATH8 cell line and reported the favorable test results to Burroughs. If the inventions were made before the NIH scientists screened "Compound S," as Burroughs contended, then the NIH scientists by definition could not be joint inventors. Conversely, if the inventions were not made until after the NIH screening took place, then the role of the NIH scientists might qualify them for joint inventorship. See 94-1527 Pet. App. 7a.

The dispute over when the inventions were made rests on an underlying disagreement over the governing test for "invention" under federal patent law. See 35 U.S.C. 100(a). Generally speaking, the act of invention involves two components, conception and reduction to practice. See 35 U.S.C. 102(g). Conception is the inventor's mental formulation of a complete idea for the product or process. *Sewall* v. *Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); 3 D. Chisum, *Patents* § 10.04, at 10-48 (1994). Reduction to practice is the process of putting the idea into effect, either by building and testing the invention ("actual" reduction to practice) or by filing an enabling patent application ("constructive" reduction to practice). 3 D. Chisum, *supra*, §§ 10.05-10.06. See also 1 *Walker on Patents* §§ 3.11-3.12 (1984).

In this case, the dispute focused on the element of conception. Although the federal patent statutes refer to conception (see 35 U.S.C. 102(g)), Congress has left the task of defining conception to the courts. The courts have relied on the judicial definition set out in *Mergenthaler* v. *Scudder*, 11 App. D.C. 264 (D.C. Cir. 1897), which states as follows:

> The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instrument, belongs to the department of construction, not invention. It is therefore the formation, in the mind of the inventor, *of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice*, that constitutes an available conception, within the meaning of the patent law.

11 App. D.C. at 276. See, *e.g.*, *Application of Tansel*, 253 F.2d 241, 243 (C.C.P.A. 1958) ("The *Mergenthaler* decision

has been repeatedly cited and approved by this court."); *Gunter* v. *Stream*, 573 F.2d 77, 80 (C.C.P.A. 1978) (following *Mergenthaler*); *Coleman* v. *Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985) (same).

Under the *Mergenthaler* standard, conception is deemed complete when the inventor can describe the invention with sufficient clarity and precision to make an "enabling" disclosure—that is, "a disclosure which would enable a person of ordinary skill in the art" to practice the invention. *Tansel*, 253 F.2d at 243; see also *Coleman*, 754 F.2d at 359; 3 D. Chisum, *supra*, § 10.04[3], at 10-160. In this case, Burroughs contended that the draft British patent application was just such an enabling disclosure and that the preparation of the draft application on February 6, 1985, demonstrated that the Burroughs scientists had conceived the inventions by that date. 94-1527 Pet. App. 7a.

Barr and Novopharm evidently did not dispute that the draft patent application was enabling. See 94-1527 Pet. App. 13a, 29a. However, they contended that in "uncertain" or "experimental" fields, such as biology and pharmacology, conception is not complete until the inventor has a "reasonable expectation" that the invention will work. Under that proposed standard, even if a person has formed an otherwise definite and permanent idea of the invention and has made an enabling disclosure, he cannot be deemed to conceive the invention until he obtains experimental data or other information that would make it reasonable for him to expect the invention to work. In this case, Barr and Novopharm contended that the results of the murine retrovirus screening (see p. 2, *supra*) did not provide a reasonable expectation that AZT would be active against HIV in human cells and that the Burroughs scientists did not have a reasonable expectation until Dr.

Broder informed them of the results of the ATH8 cell line screening. See 95-1527 Pet. 9.

4. In June 1993, the district court commenced a jury trial of the parties' patent infringement and joint inventorship claims. During that trial, Barr and Novopharm sought to introduce evidence bearing on their "reasonable expectation" theory of conception. The district court disallowed the evidence on the ground that, as a matter of patent law, conception does not require the inventor to have a reasonable expectation that the invention will work. After allowing Barr and Novopharm to submit offers of proof on the reasonable expectation issue, the district court entered judgment for Burroughs as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure. See 94-1527 Pet. App. 25a-37a.

The Federal Circuit affirmed the judgment with respect to five of the six patents and remanded (for reasons that are not relevant here) with respect to the remaining patent. See 94-1527 Pet. App. 1a-19a. The court of appeals agreed with the district court that the legal test for conception does not include a "reasonable expectation" requirement. *Id.* at 9a-16a. The court held that, as long as the inventor "had an idea that was definite and permanent enough that one skilled in the art could understand the invention," his "belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception." *Id.* at 9a, 10a.

The Federal Circuit concluded that Burroughs' preparation of the enabling draft British patent application demonstrated that the Burroughs scientists "had formulated a definite and permanent idea of the inventions" before the NIH scientists confirmed that AZT was active against HIV. Hence, the NIH scientists could not be joint inventors. 94-1527 Pet. App. 13a-14a, 15a. The court agreed with Barr and Novopharm that the NIH scientists

had been more than "a pair of hands" in carrying out the ATH8 screening, but reasoned that the screening merely "confirmed the operability of the inventions" and was "part of the reduction to practice" rather than part of the conception. *Id.* at 14a-15a.

DISCUSSION

The legal questions presented in this patent case arise in a dispute involving AZT, which is currently the most widely used medicine for the treatment of AIDS. The outcome of this dispute may affect the price, and consequently the availability, of AZT to AIDS patients. The AIDS epidemic is one of this country's most pressing health problems, and the United States has a strong public health interest in facilitating the availability of AZT to AIDS patients at an affordable price. Nevertheless, the resolution of this case must ultimately turn on the proper construction of federal patent law, which embodies long-standing principles governing inventorship. Indeed, the incentives of the patent system, including the opportunities that system provides for the recoupment of expensive research costs, help to provide hope that more effective means than AZT for treating or preventing AIDS will be forthcoming.

1. The primary issue here is whether an inventor must have a reasonable expectation that an invention will work in order to conceive the invention within the meaning of patent law. In our view, the Federal Circuit's decision is correct. The court's rejection of the "reasonable expectation" standard rests on a sound interpretation of the controlling judicial precedents and does not conflict with any decision of this Court or any other court. The Federal Circuit's decision is also consistent with underlying principles of patent policy. Contrary to Barr's suggestions, it is not likely to impede the development of

future medical treatments for AIDS and other diseases. Accordingly, we do not believe that further review by this Court is warranted.

a. The Federal Circuit did not write its decision on a blank slate. This Court recognized the basic requirements of conception in *The Telephone Cases*, 126 U.S. 1 (1888), which upheld Alexander Graham Bell's right to a patent for the telephone. The Court ruled that Bell had established his conception of the invention when he applied for a patent, even though at that time "he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line." *Id.* at 535. The Court rejected the argument that "Bell had not in fact completed his discovery" (*ibid.*), explaining as follows:

> The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practical way of putting it into operation. This Bell did.

Id. at 536. The District of Columbia Circuit refined that principle in *Mergenthaler*, and for nearly a century, the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals (CCPA), have followed the definition of conception set forth therein. See pp. 6-7, *supra*. That definition does not ask whether the inventor knows, or has reason to believe, that his invention works. Instead, it simply asks whether the inventor has developed "a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Mergenthaler*, 11 App. D.C. at 276 (emphasis omitted).

Under the *Mergenthaler* standard, the test of conception is whether the inventor "is able to make a disclosure which would enable a person of ordinary skill in the art to practice the disclosure without extensive research or experimentation." *Applegate* v. *Scherer*, 332 F.2d 571, 572 (C.C.P.A. 1964). According to the Federal Circuit, Barr and Novopharm conceded that Burroughs' draft British patent application "would teach one skilled in the art to practice the inventions." 94-1527 Pet. App. 13a; see *id.* at 29a. Consequently, Burroughs had satisfied the prevailing test for conception by February 6, 1985, before the NIH scientists screened "Compound S" against the ATH8 cell line.

Contrary to Barr's suggestions (94-1527 Pet. 16-17), neither the Federal Circuit nor the CCPA has ever held that conception is incomplete until the inventor demonstrates a "reasonable expectation" that the invention will work. Indeed, the CCPA specifically rejected proposed tests of conception that would have looked to the inventor's knowledge, or lack of knowledge, about the efficacy of his invention. The CCPA's decision in *Applegate* is illustrative. In that case, a federal agency was conducting a screening program to find compounds that could control sea lampreys. A chemical company contacted the agency to suggest that one of its compounds might be effective. The company sent a sample to the agency, which tested it and found that it was effective. The company and the agency then filed rival patent applications, with each party claiming sole inventorship. See 332 F.2d at 571-572.

The agency argued that the company did not conceive the invention because, at the time that it sent the sample for testing, it did not know whether the compound would work. The CCPA squarely rejected that argument in terms similar to those used by this Court in *The Telephone Cases*, *supra*. The CCPA stated:

> [The agency] seem[s] to propose that there cannot *be* a conception of an invention of the type here involved in the absence of knowledge that the invention will *work*. Such knowledge, necessarily, can rest only on an actual reduction to practice. To adopt this proposition would mean, as a practical matter, that one could never communicate an invention thought up by him to another who is to try it out, for, when the tester succeeds, the one who does no more than exercise ordinary skill would be rewarded and the innovator would not be. Such cannot be the law. A contrary intent is implicit in the statutes and in a multitude of precedents.

332 F.2d at 573-574.

The CCPA's decision in *MacMillan* v. *Moffett*, 432 F.2d 1237 (C.C.P.A. 1970), makes the same point. In *MacMillan*, one company selected antiperspirant compounds for testing by another company. Moffett, a scientist employed by the first company, selected 69 compounds for screening, and the second company's scientists found that one of those compounds was highly effective. The CCPA held that Moffett was the sole inventor, even though he had "no knowledge that [the effective compound] would have new and unexpected properties over the prior art and over the other 68 compounds he selected." *Id.* at 1239. The court held that Moffett's "reasons or lack of reasons for including [the compound] are not relevant to the question of conception. The important thing is that he did think in definite terms of the method claimed." *Ibid.*; see 3 D. Chisum, *supra*, § 10.04[4], at 10-68 to 10-69.[1]

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[1] Strictly speaking, precedents such as *Applegate* and *MacMillan* hold only that an inventor does not need to *know* that his invention works. They do not hold that the inventor does not need a "reasonable expectation" that the invention works. Their reasoning, however, is at

In the lower court proceedings, Barr attempted to support its "reasonable expectation" test by reference to cases in which an invention was simultaneously conceived and reduced to practice. See *Smith* v. *Bousquet*, 111 F.2d 157 (C.C.P.A. 1940); *Alpert* v. *Slatin*, 305 F.2d 891, 894 (C.C.P.A. 1962); see generally 3 D. Chisum, *supra*, § 10.04[5]. According to Barr, those cases demonstrate that conception in speculative fields cannot occur until the inventor acquires a reasonable basis (through experimentation or otherwise) for believing that his invention will work. See 94-1527 Pet. App. 10a. The Federal Circuit carefully reviewed the "simultaneous conception and reduction to practice" cases and concluded that they do not involve an exception to the *Mergenthaler* test, nor do they require proof of "reasonable expectation" as an element of conception in speculative fields of research. See 94-1527 Pet. App. 10a-12a.

As the Federal Circuit explained, the CCPA's opinions in *Smith* and *Alpert* deal with an evidentiary problem under the *Mergenthaler* test—the difficulty of determining when an inventor who is proceeding by "trial and error" (*Alpert*, 305 F.2d at 894) has formed a definite and fixed idea of the ultimate invention. See 94-1527 Pet. App. 10a-11a. In that situation, "the reduction to practice can be the most definitive corroboration of conception, for where the idea is in constant flux, it is not definite and permanent." *Id.* at 11a. In this case, by contrast, the enabling draft British patent application supplied the necessary evidence that Burroughs had arrived at a "definite and permanent" idea of the patented methods of

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odds with a "reasonable expectation" test, for that test rests squarely on the premise that conception is complete as soon as the inventor "think[s] in definite terms of the method claimed." *MacMillan*, 432 F.2d at 1239.

using AZT to treat AIDS. Hence the evidentiary problem involved in cases such as *Smith* was not presented. *Id.* at 16a. See 3 D. Chisum, *supra*, § 10.04[5], at 10-75.[2]

Barr also relied below on a statement in *Biel* v. *Chessin*, 347 F.2d 898 (C.C.P.A. 1965), that when someone invents "a method of treating the human body" with a compound, conception requires "some * * * reasonable understanding or appreciation of the fact that the compound would work." *Id.* at 902-903. The Federal Circuit noted, however, that the quoted language in *Biel* was dictum that had not been treated as controlling in subsequent cases. 94-1527 Pet. App. 10a n.7. That court, which is the CCPA's successor, acted appropriately in declining to give force to that prior dictum. See *Metropolitan Stevedore Co.* v. *Rambo*, 115 S. Ct. 2144, 2149 (1995).

The Federal Circuit's reading of the "simultaneous conception and reduction to practice" cases is consistent with longstanding patent law principles, and its rejection of *Biel*'s never-applied dictum is sound. Prior to the Federal Circuit's ruling in this case, its case law may have created a legitimate question concerning the governing test for conception in "speculative fields," but the court has now dispelled whatever uncertainty existed among its own precedents and has obviated the need for further review. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam) ("It is primarily the task

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[2] The CCPA itself recognized that the concept of "simultaneous conception and reduction to practice" is "rarely applied." *Alpert*, 305 F.2d at 894. It confined that principle to priority disputes involving independent inventors, and it declined to invoke the principle in originality disputes involving collaborative research efforts. See *Applegate*, 332 F.2d at 573; *MacMillan*, 432 F.2d at 1240 ("*Applegate* * * * made it abundantly clear that such a doctrine does not apply in cases where the issue is originality or derivation."); 3 D. Chisum, *supra*, § 10.04[5], at 10-72.

of a Court of Appeals to reconcile its internal difficulties.").

b. The Federal Circuit correctly recognized that Barr's proposed "reasonable expectation" standard is not an established element of existing patent jurisprudence. Barr disagrees with that conclusion, but its principal arguments in this Court rest on policy considerations relating to "patent monopolies." See 94-1527 Pet. 13-14. Barr's policy arguments are not persuasive.

Barr argues that its "reasonable expectation" standard would increase the incidence of joint inventorship and thereby reduce the occurrence of "patent monopolization." See 94-1527 Pet. 16. Barr suggests that when a single inventor or firm holds a patent, it encourages an undesirable "patent monopoly" in which the patentholder is free to charge whatever the market will bear, without having to face competition from other firms selling the same invention. Barr theorizes that when two or more inventors hold a patent, greater competition and lower prices will result, because each inventor has an independent right under 35 U.S.C. 261-262 to market the invention. 94-1527 Pet. 16.

Barr's "patent monopolization" argument has several shortcomings. First, it is in significant tension with the fundamental policies of the patent laws. See U.S. Const., Art. I, § 8, Cl. 8 ("To promote the Progress of Science and useful Arts."). Congress has crafted a patent system that provides a right to exclude, which amounts to a limited legal monopoly as an incentive for the development of socially useful inventions. *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). Congress has determined the confines of that right, imposing prerequisites (such as utility, novelty, and non-obviousness, 35 U.S.C. 101-103) and restrictions (such as durational limitations, 35 U.S.C. 154). But Barr has pointed to nothing in the patent laws

expressing Congress's intent to promote joint inventorship as a means of limiting that right. At bottom, Barr's argument is an invitation to this Court to assume a legislative role. Barr asks this Court to modify the longstanding test for conception to alter the balance that Congress has struck to spur socially beneficial inventive efforts.[3]

Second, Barr's surmise that a "reasonable expectation" standard would encourage joint inventorship is open to serious question. Barr's argument assumes that a firm that does not yet have a "reasonable expectation" about its invention's efficacy will nonetheless turn the invention over to another firm for testing without first taking steps to protect itself against the potential loss of exclusive patent rights. That assumption is highly dubious. The first firm can generally ask the second firm to yield by contract whatever patent rights the second firm might otherwise acquire through the testing process. If the second firm is unwilling to conduct the testing under those terms, the first firm may be able to find someone else who is willing and able to perform the tests on the same terms. Alternatively, the first firm may be able to develop the necessary testing capabilities "in house," and presumably will do so if the potential economic payout from the invention makes it worthwhile.

Third, even when a "reasonable expectation" requirement would lead to jointly held patent rights in a particu-

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[3] The judicial resolution of patent disputes may affect the economic power of market participants, and courts may take into account the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly" when they decide patent law issues. *Brenner*, 383 U.S. at 534. But the courts evaluate that factor based on congressional intent and not merely on the basis of sentiments regarding the desirability of the durationally limited rights authorized by the patent law. See, *e.g.*, *id.* at 529, 532-535.

lar case, there is little reason to think that the result will be greater competition and lower prices for the patented invention. Joint inventors ordinarily will have a common interest in maximizing any profits made possible by the patent. As a result, joint inventors will have a strong mutual incentive not to engage in price competition.[4]

In addition to the patent "monopolization" argument, Barr suggests that the Federal Circuit's decision is unsound because it grants patent rights too freely, or at least prematurely, to companies that rely on unsupported speculation rather than research. Barr raises the specter that a firm can "become an inventor by claiming that any number of identified compounds will cure any number of identified diseases" (94-1527 Pet. 15), without believing (or having any basis for believing) that the compounds

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[4] In this case, a federal agency performed the testing at issue. Barr perhaps believes that its "reasonable expectation" standard would broaden the government's joint inventorship rights when it tests products and thereby reduce the prospect of monopoly pricing in those fields where the government conducts research. Such a belief, however, would be very speculative. It is true that government does not share the profit-maximization objectives of a private firm; indeed, federal agencies are prohibited from granting exclusive licenses that would substantially lessen competition or result in undue concentration of economic power. See 35 U.S.C. 209(c)(2). But to the extent that Barr's "reasonable expectation" test would tend to make the government a joint inventor, the government's unwillingness to take part in monopoly pricing would correspondingly increase the incentive for private firms to avoid the joint inventorship "problem" in the first place. The firm might do so either by using non-government testing resources or by entering into pre-testing contractual arrangements that limit the government's patent rights. See Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a (1988 & Supp. V 1993) (authorizing federal laboratories to enter into "cooperative research and development agreements" with private companies and other "collaborating parties" that determine patent and licensing issues at the outset of government involvement); see also S. Rep. No. 283, 99th Cong., 2d Sess. 11 (1986).

actually cure the diseases. Barr implies that firms will be able to acquire new patent rights simply by drawing up lists of compounds and diseases. *Id.* at 18-19.

That scenario is not, in our view, a realistic one. First, even under the *Mergenthaler* standard, conception is not deemed to be complete until the invention has been embodied in an enabling disclosure. See 94-1527 Pet. App. 8a-9a, 13a; *Coleman*, 754 F.2d at 359 ("Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his 'completed thought expressed in such clear terms as to enable those skilled in the art' to make the invention.") (quoting *Field* v. *Knowles*, 183 F.2d 593, 601 (C.C.P.A. 1950)). Second, merely conceiving an invention, without more, does not confer any patent rights whatsoever. The inventor must reduce the invention to practice, either actually or constructively (see p. 6, *supra*), and must do so promptly or risk losing whatever patent rights he might otherwise be entitled to. See 35 U.S.C. 102(g); accord *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390, 400 (1926). Even after conception and reduction to practice are complete, moreover, the inventor must be able to show that his invention satisfies the patent law's substantive requirements for patentability, such as novelty, utility, and non-obviousness. See 35 U.S.C. 101-103; accord *Brenner*, 383 U.S. at 528-536. The traditional test for conception employed by the Federal Circuit in this case does not eliminate those additional legal requirements for obtaining patents, and there is accordingly no reason for companies to respond to this decision, as Barr predicts (94-1527 Pet. Reply Br. 1-2), by spending their time fruitlessly drawing up arbitrary lists of compounds and diseases and putting them into draft patent applications.

On the other side of the coin, adoption of a "reasonable expectation" test would impose a potentially significant

burden on the patent process by complicating the task of proving conception. Under current law, the Patent and Trademark Office and the courts resolve conception disputes by requiring the inventor to present evidence that he had a definite and permanent idea comprising the invention. The inventor can be expected to create documentary evidence on that matter, such as Burroughs' draft patent application or an inventor's work diary, in the ordinary course of developing the invention. There is no reason to believe, however, that inventors routinely develop documentary evidence of their expectations concerning their inventions' effectiveness. As a result, if the approach urged by Barr were to be adopted, the parties and courts would be faced with the task of retrospectively constructing and evaluating a record of the inventor's subjective knowledge and beliefs. That task would encumber administrative proceedings and patent litigation with additional and, in our view, unnecessary uncertainty and expense.

In sum, we see no significant basis for believing that adoption of a "reasonable expectation" test would be desirable as a matter of patent policy. The test would be an administrative encumbrance but would not appear likely to change either the incentives for collaborative development of inventions or the allocation of patent rights among collaborators. There is no reason to believe that the substantial public interest in encouraging development of beneficial products, such as new medicines, would be furthered if the test were to become law.

2. Novopharm's petition (No. 94-1531) presents two additional objections to the decision below. Neither of them warrants review by this Court.

First, Novopharm argues that there was "sufficient evidence in the record" (94-1531 Pet. 8) to foreclose the district court from entering judgment as a matter of law

under Federal Rule of Civil Procedure Rule 50(a). Novopharm does not contest the legal standard for conception employed by the court of appeals, but argues only that "the totality of the evidence" (94-1531 Pet. 12) created an issue of fact for the jury to decide under that standard. *Id.* at 8. The question whether Novopharm's offer of proof (94-1531 Pet. App. 46a-58a) was sufficient to create a jury question under the Federal Circuit's legal standard is a factbound matter that does not warrant further review. See, *e.g.*, *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

Second, Novopharm argues (94-1531 Pet. 13-14) that once the court of appeals determined that the NIH scientists acted as more than a mere "pair of hands" in screening "Compound S" (94-1531 Pet. App. 18a), the court should have deemed the NIH scientists to be joint inventors as a matter of law. That argument rests on a *non sequitur*. The degree of skill and expertise employed by the NIH scientists might have been relevant to the issue of joint inventorship if the Burroughs scientists had not already conceived the patented inventions when the NIH scientists performed their tests. But once it is recognized that under the findings in this case conception was complete by February 6, 1985, it follows that the skill employed by the NIH scientists thereafter is irrelevant.

CONCLUSION

For the foregoing reasons, the petitions for a writ of certiorari should be denied.

Respectfully submitted.

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